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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,682	05/16/2001	Ning Li	031855.0007	1553

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BROBECK, PHLEGER & HARRISON, LLP  
ATTN: INTELLECTUAL PROPERTY DEPARTMENT  
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WASHINGTON, DC 20005

EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/05/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/855,682

Applicant(s)

LI ET AL.

Examiner

Juliet Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Priority*

1. Applicant is referred to rule 1.78(2), which states, in part,

“Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. **This reference must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is not extendable.** Unless the reference required by this paragraph is included in an application data sheet (§ 1.76), the specification must contain or be amended to contain such reference in the first sentence following the title (emphasis added).”

2. The first line of the specification in the instant case refers to provisional application 60/088963. However, this provisional application had expired at the time this application was filed, and thus the two applications were not co-pending. There is no reference to any other co-pending applications in the first line of the specification, and there is no application data sheet with this application. Therefore, the effective filing date of the instant application is the actual filing date, May 16, 2001.

### *Sequence Rules*

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821-1.825 because there are disclosed sequences in the specification that are not properly identified. See, for example, pages

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3, 4, 5, and 10. Applicant is required to submit an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention relates to methods for screening pigs to identify pigs with genomic polymorphisms in the FSH  $\beta$ -subunit sequence which are associated, by statistical correlation, to increased or decreased litter size. The rejected claims are broadly drawn to methods for screening pigs to determine those more likely to produce larger litters and or those less likely to produce larger litters by determining which FSH  $\beta$ -subunit allele is present, of any possible FSH  $\beta$ -subunit alleles. Such a claim encompasses the use of any possible mutation or polymorphism in the FSH  $\beta$ -subunit that has a correlation with increased litter size in pigs. However, the specification only describes a single polymorphism in the FSH  $\beta$ -subunit, a specific inserted retroposon allele, which was linked to litter size. Thus, at the time of filing, applicant was only in possession of methods of screening pigs to determine those more likely to produce larger litters, and/or those less likely to produce larger litters which comprises to detecting the specific

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insertion (or absence) of a retroposon which creates 516 and 224 bp fragments the FSH  $\beta$  subunit amplification products. Thus, applicant has express possession of only one species in a genus which comprises at least hundreds of different possibilities.

With regard to the written description, all of these claims encompass the use of different polymorphisms from those disclosed in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the specific structure of a single polymorphism has been disclosed. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of methods which utilize any polymorphism other than the single retrotransposon described in the specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 are indefinite for failing to recite a final process step which agrees back with the preamble. For example, Claims 1 is drawn to a method for screening pigs to determine those more likely to produce larger litters, yet the claims recite a final step of determining which FSH  $\beta$ -subunit allele(s) is present in the genome of individual pigs. The claims do not set forth the relationship between the determining which FSH  $\beta$ -subunit allele(s) is present in the genome of individual pigs and determining those more likely to produce larger litters and therefore, it is not clear whether the claims are intended to be drawn to a method determining those more likely to produce larger litters or a method for determining which FSH  $\beta$ -subunit allele(s) is present in the genome of individual pigs.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yaofeng *et al.* (Science in China Series C Life Sciences, (Dec. 1998) Vol. 41, No. 6, pp. 664-668).

Yaofeng *et al.* teach a method for screening pigs to determine those more likely to produce larger litters, and or those less likely to produce larger litters, which method comprises

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determining which FSH  $\beta$ -subunit allele(s) is/are present in the genome of individual pigs (p. 665). Yaofeng *et al.* employ methods which include the steps of (i) obtaining a sample of pig nucleic acid; and (ii) analyzing the nucleic acid obtained in (i) to determine which FSH  $\beta$ -subunit allele(s) is/are present. Yaofeng *et al.* specifically teach that this method "will have a great consequence in swine breeding because the FSh  $\beta$  gene can be applied to marker-assisted selection to speed up the genetic improvement of litter size (p. 668)."

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6291174. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '174 patent are a species of the instant claim and thus anticipate the instant claims.

### ***Conclusion***

11. No claims are allowed.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

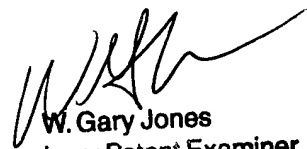
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C. Einsmann  
Examiner  
Art Unit 1655

May 20, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600